From the
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2004/001023	02.04.2004	02.04.2003

International Patent Classification (IPC) or both national classification and IPC
A61N1/08, A61N1/36, A61N1/05, A61N1/378, A61B5/11

Applicant
NEUROSTREAM TECHNOLOGIES INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

FEB 2, 2005

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Fischer, O Telephone No. +49 89 2399-2327

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2004/001023

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was field, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

   ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	8,9,16-19,22
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-7,10,15,20,21,23-37
Industrial applicability (IA)	Yes:	Claims	1-37
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: CA-A-2 097 857 (HOFFER ANDY ;HAUGLAND MORTEN (DK); SINKJAER THOMAS (DK)) 5 December 1994
   D2: WO 01/60445 A (NEURODAN AS ;HAUGLAND MORTEN (DK); SINKJAER THOMAS (DK)) 23 August 200
   D3: WO 02/13695 A (BARRISKILL ANDREW ;DUNCAN MICHAEL ROBERT (AU); NEOPRAXIS PTY LTD) 21 February 2002
   D4: US 2002/188331 A1 (DEMCHAK JEFFREY A ET AL) 12 December 2002
   D5: US-B1-6 415 181 (GREENINGER DANIEL R ET AL) 2 July 2002

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 8, 9, 16-19 and 22 is not new in the sense of Article 33(2) PCT.

2.1 Claim 8

Document D1 (see in particular p. 7, l. 23 - p. 13, l. 9 and figs. 1A-B) discloses a fully implantable (p. 11, l. 12-16) nerve stimulation system for treating foot drop, comprising:

- one or more nerve cuffs (4) having electrodes therein that detect signals from and/or deliver stimulation to a nerve fibre (see fig. 1A);
- a sealed closed-loop control unit (2) that is connected to receive signals from at least one electrode in a nerve cuff and to deliver stimulation pulses to at least one electrode in order to produce a desired physiological response, the closed-loop control unit including:
- an electrical power source;
- a processor (LOGIC),
- a number of signal conditioning circuits (AMP, RBI);
- a programmable switch controlled by the processor to connect an electrode to a

signal conditioning circuit;
- at least one stimulation circuit (STIM) that delivers a stimulation pulse to one or more of the electrodes;
- wherein the processor detects the occurrence of heel contact by filtering the output signal produced by the signal conditioning circuit (see fig. 1B).

Further also document D2 (see in particular p. 33, l. 27 - p, 39, l. 11 and figs. 9-13) shows a fully implantable nerve stimulation system for treating foot drop, comprising:
- one or more nerve cuffs having electrodes therein that detect signals from and/or deliver stimulation to a nerve fibre (see figs. 8-9);
- a sealed closed-loop control unit (103) that is connected to receive signals from at least one electrode in a nerve cuff and to deliver stimulation pulses to at least one electrode in order to produce a desired physiological response, the closed-loop control unit including:
- an electrical power source;
- a processor (p. 32, l. 1-18 and p. 34, l. 30 - p. 35, l. 8),
- a number of signal conditioning circuits (114);
- a programmable switch (switch network) controlled by the processor to connect an electrode to a signal conditioning circuit;
- at least one stimulation circuit (115) that delivers a stimulation pulse to one or more of the electrodes;
- wherein the processor detects the occurrence of heel contact by filtering the output signal produced by the signal conditioning circuit (see fig. 13).

2.2 Claim 9

Claim 9 corresponds to claim 8 with the following features added: the processor further compares the filtered output signals with the unfiltered output signals to detect a rising or falling ramp (heel contact or heel/toe lift) in the output signals and the processor causes at least one stimulation pulse to be delivered to an electrode upon detection of a toe lift event.

However these features are also disclosed in D2 (see p. 16, l. 7-21 and fig. 13). Indeed, the signals of fig. 13 correspond to heel contact or heel/toe lift and are used as stimulation control signals in order to deliver stimulation pulses upon detection of

heel contact or heel/toe lift.

2.3 Claim 19

Claim 19 is a generalisation of claim 9, wherein the processor detects physiological event signals (e.g. heel contact) from the processed nerve signals and delivers a stimulation pulse to an electrode upon detection of a physiological event (i.e. in response to heel contact or heel lift). Such a system is disclosed in D2 and therefore, the subject-matter of claim 19 also lacks novelty in the sense of Article 33 (2) PCT.

2.4 Claims 16-18

The subject-matter of claims 16-18 is anticipated by D2 (see p. 19, l. 25-33 and p. 28, l. 21-p. 29, l. 16 and fig. 10).

2.5 Claim 22

The device of D2 (see fig. 9) contains a programmable switch (switch network) that selectively couples a signal conditioning circuit to an electrode.

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7, 10, 15, 20, 21, 23-37 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1 Claim 1

Claim 1 merely corresponds to a combination of claims 19 and 22 with the difference that the processor selectively enables the number of signal conditioning circuits, the programmable switch and the at least one stimulation circuit to lengthen the life of the electrical power source.
However, the feature of shutting down circuit components which are not used has already been employed for the same purpose in other implantable stimulation devices, see document D5, col. 3, l. 31-43. It has been a constant endeavour in the field of implantable stimulation devices to reduce power consumption and therefore

it would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to the device of D1 or D2, thereby arriving at the claimed subject-matter.
Consequently, the subject-matter of claim 1 lacks an inventive step within the meaning of Article 33 (3) PCT.

3.2 Claim 25

Claim 25 merely corresponds to claim 8 with the difference that the control unit further comprises a sensor for producing a signal indicative of an angle of a patient's thigh and the processor is programmed to operate in a plurality of modes that are dependent in part on the sensed angle of the patient's thigh.

However, these features have already been employed for the same purpose in a similar implantable FES system, see D3 (p. 8, l. 13 - p. 9, l. 18 and p. 12, l. 14 - p. 17, l. 25 and figs. 1, 2, 5). It is therefore obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to the device of D2, thereby arriving at the claimed subject-matter.
Consequently, the subject-matter of claim 25 also lacks an inventive step within the meaning of Article 33 (3) PCT.

3.3 Claim 37

The subject-matter of claim 37 differs from D2 in that the processor is programmed to operate in a user initiated exercise mode such that stimulation signals are delivered to a nerve for a period of time to exercise the patient's muscle. However, this feature becomes obvious over the combination of D2 with D4: indeed D4 (see in particular p. 10, paragraph [0108] and figs. 6, 7, 12) relates to a similar neurostimulator in which specific training programs are incorporated and executed according to programmed timing parameters. Hence, the subject-matter of claim 37 also lacks an inventive step within the meaning of Article 33 (3) PCT.

3.4 Claims 2-4

As seen above, the devices of D1 and D2 both process the nerve signal using the

RBI (Rectified Bin-Integration) method to detect heel contact and/or toe lift and then use this signal as stimulation control. Hence, the subject-matter of claims 2-4 also lacks an inventive step (Article 33 (3) PCT).

3.5 Claims 5-7, 10-15, 20, 21, 23, 24, 26-36

Dependent claims 5-7, 10-15, 20, 21, 23, 24, 26-36 seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step. The features of claims 6-7, 10, 27, 28, 30-33 are already known (see D3, figs. 1, 2, 5 and corresponding passages of the description) and it would be obvious for the skilled person to incorporate them in a device like D1 or D2 to arrive to the claimed subject-matter.
The remaining claims relate mainly to the problem of minimising power consumption which has been a constant endeavour in the field of implantable stimulation devices. The features of these claims concern slight changes and straightforward possibilities from which come within the scope of the customary practice followed by skilled persons in the field of implantable stimulation devices, and which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill (Article 33 (3) PCT).

Re Item VIII

Certain observations on the international application

The present set of claims does not comply with the requirements of Article 6 PCT as to the required conciseness of the claims. Indeed, claims 1, 8, 9, 19, 25 and 37 have been drafted as separate independent claims, but they appear to relate effectively to the same subject-matter and differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.
In the present case, it seems **not appropriate to define** the relevant subject-matter in **more than one independent system claim**.